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EXAMINER	
MCCORMICK, MELENIE LEE	

ART UNIT	PAPER NUMBER
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/660,737

Applicant(s)

MARTIN, MICHAEL Z.

Examiner

Melenie McCormick

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 15-23 is/are pending in the application.
- 4a) Of the above claim(s) 15-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's remarks with claim amendments submitted 23 July 2007 have been received and considered.

Newly submitted claims 15-23 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claims are drawn to a method of extracting a soluble composition from a raw plant material. This is independent and distinct from the originally presented invention which was drawn to a soluble composition.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 15-23 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 11-14 have been cancelled.

Claims 1-10 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 is indefinite and confusing due to the phrase "wherein the respective weight ratios of substances within each selected class are within 100% of the same ratio for substances in the plant material". Although difficult to understand, the phrase has been interpreted to mean that the substances within the extract composition present in the composition within 100% of the ratio of the substances which are present in the plant. It is not clear, however, what is meant by "within 100%". Does this mean from 0% to 100% or does it mean that the substances in the composition are present in exactly (100%) the same ratio as the substances in the plant?

Claim 7 is rendered vague and indefinite due to the phrase "in relative ratios that mimic their ratios in the unextracted plant material". It is not clear what is meant by the term "mimic". It is not clear exactly how the ratios in the composition resemble the ratios in unextracted plant material.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Response to Arguments

Applicants argue that the claims are not vague and indefinite because the instant specification explains that the ratios of phytochemicals in the extracts are within 300%, 200%, 100%, 50% or 25% of the ratios of phytochemicals in the plant material. This is not persuasive, because it remains unclear what this limitation entails. Are these ratios within 100% in the sense that they are 0-100% of the amount in the un-extracted material, which is a broad range, or are the ratios exactly the same as the amount in the

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un-extracted plant material, which would be a very narrow range? Applicants also argue that the term 'mimic' is not unclear. This is not persuasive, as the use of the term 'mimic' does not make clear exactly what the amount of the various phytochemical present in the instantly claimed extract is. Plants will differ in the amount of various phytochemicals present from harvest to harvest. Therefore, by identifying the amount of components present in the instantly claimed extract as compared to un-extracted plant material, the instant claims fail to particularly point out and distinctly claim how much of each component the extract actually contains. Therefore, the claims are vague and indefinite, as a skilled artisan would not understand the metes and bounds of the claims.

The rejection is therefore deemed proper and is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 stand rejected under 35 U.S.C. 103(a) as obvious over Walker et al. (US 5,474,774) for reasons set forth in the previous Office Action, which are restated below.

The claims are drawn to a soluble composition extracted from *Vaccinium macrocarpon* comprising multiple substances within at least 3 classes selected from the

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group consisting of carotenoids, anthocyanins, and alkaloids, wherein the respective weight ratio of substances within each selected class are within 100% of the same ratio for substances in the plant material and wherein the relative proportion of free sugar in the composition is less than 20% of the free sugar in the plant. The claims are further drawn to the composition wherein additional classes of substances are present, wherein less than 1% of the original water content of the plant material remains, and wherein the relative proportion of free sugar in the composition is less than 10% or less than 5% of the free sugar found in the plant material.

Walker et al. beneficially teach an extract made from *Vaccinium macrocarpon* (see e.g. col 1, lines 42-45 and 64-65). Walker et al. further teach that the extract is enriched to a similar degree in concentration of flavonoids and polyphenolic compounds as juices which are derived from the plant (see e.g. col 1, lines 57-59). The extract composition disclosed by Walker et al. would intrinsically contain the substances from the classes instantly claimed, as these substances are naturally occurring in cranberry plant material. Because Walker et al. teach that flavonoids and polyphenolic compounds are present in a similar degree as in the plant material, the composition taught by Walker et al. read on the instantly claimed extract composition containing multiples substances in ratios which mimic their weight ratio in the plant material. This is especially true in light of the fact that Applicants have not established what these weight ratios are. Walker et al. further teach that the extract has a greatly reduced sugar content, which reads on less than 10% and less than 5% of the free sugar found in the plant material (see e.g. col 2, lines 49-52). Because the composition beneficially taught

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by Walker et al. is an extract and may be in powder form, it would necessarily have a lower water content than the original plant material (see e.g. col 3, lines 29-40). Walker et al. further disclose that the extract is soluble (see e.g. col 3, Table 1).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare an extract composition with the properties instantly claimed. One of ordinary skill in the art would have been motivated and would have had a reasonable expectation of success in doing so based upon the beneficial teaching of Walker et al. that such an extract has been prepared. The adjustment of particular conventional working conditions (e.g. specific amounts of individual components within the extract composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

With respect to the USC 103 rejection above, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' *Vaccinium macrocarpon* extract composition differs and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the

reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Response to Arguments

Applicants argue that Walker et al. do not does not suggest the instantly claimed Vaccinium extract. This is not persuasive, because, as previously stated, Walker et al. teach an extract made from *Vaccinium macrocarpon* and further teach that the extract is enriched to a similar degree in concentration of flavonoids and polyphenolic compounds as juices which are derived from the plant. This would reasonably suggest to a person of ordinary skill in the art that an extract from *Vaccinium macrocarpon* with particular amounts of phytochemicals present in amounts similar to the native plant is useful and can be produced. Applicants have pointed to a portion of the instant specification which states that methods in the literature for isolating bioactive molecules or groups of molecules originated from basic research on small samples and are not practical for commercial use. This excerpt does not distinguish Applicants instantly claimed composition from the composition taught by Walker et al. Applicants claims are drawn to an extract which would be obvious over the extract taught by Walker et al. Applicants further argue that Walker et al. teach an extract which has anti-adhesion activity, contains flavonoids and other polyphenols. Nonetheless, this Applicants have not provided evidence that this composition would be significantly different from the instantly claimed extract. Walker teaches an extract which is enriched with flavonoids and polyphenolic compounds and would therefore suggest to a person of ordinary skill

in the art a *Vaccinium macrocarpon* extract composition similar to the instantly claimed invention. This is especially true because it is not clear exactly how much of each component is present in the instantly claimed extract. Applicants argue that the non-established weight ratios of the particular components instantly claimed is irrelevant because the weight ratios mimic the weight ratios of un-extracted plant material. This is not persuasive, because, as previously stated, Applicants have not made clear exactly what is present in the instantly claimed extract and in what amount the components are present. Therefore, because the claim language does distinctly claim the extract, the instantly claimed invention remains obvious over the extract taught by Walker et al. Please also note that, as previously stated, the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' *Vaccinium macrocarpon* extract composition differs and, if so, to what extent, from that of the discussed reference.

The rejection is therefore deemed proper and is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melenie McCormick

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Examiner
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CHRISTOPHER R. TATE
PRIMARY EXAMINER